REMARKS

Claims 1-19 and 22-34 are pending in this application. As a result of claim amendments in this Response to Office Action, claims 1-19 and 22-34 will still be pending in this application.

Applicants first thank the Examiner for her withdrawal of the restriction/election requirement from the March 26, 2003 Office Action.

Objections to the Specification

In the Office Action dated August 14, 2003, the Examiner noted the use of trademarks Enzogenol and Pycnogenol in the specification and stated that these trademarks should be capitalized in the specification and should be accompanied by the generic terminology. In response, Applicants note that they fully understand the proprietary nature of trademarks and the importance of trademarks for identification of the source of goods bearing the marks. Applicants contend, however, that in all but isolated instances Applicants' use of these marks in the specification is consistent with proper trademark usage. For example, in the specification at page 7, line 28 – page 8, line 8, Applicants describe the proprietary products ENZOGENOL™ and PYCNOGENOL™ as bark-extract anti-oxidants. Also, in virtually all instances in the specification where the marks "Enzogenol" and "Pycnogenol" are used, the marks either have been written in capital letters or have been followed by the designation "TM" or both. Instances in the specification where this is not the case are amended in this Response.

In addition, the Examiner objected to the disclosure because page 24 of the specification is in non-English language, and the Examiner requires an English translation of page 24. Applicants note that page 24 comprises the original Japanese-language printout of the results of the efficacy tests performed using various embodiments of the present invention, which results were later translated into English and set forth in the application at pages 20-22 (and in part at page 23). As a result, page 24 of the application is superfluous and need not be further included in the application. Therefore, Applicants have herein deleted page 24 from the application and request that the objection be withdrawn.

Furthermore, page 23 sets forth the end portion of the results of the efficacy tests set forth in English at pages 20-22 of the application. This page appears to have been a vestige of a prior version of the document and contains merely repetitive material. Therefore, because page 23 of the application is superfluous and need not be further included in the application, Applicants have herein deleted page 23 from the application.

Rejections Under § 112

The Examiner has rejected claim 22 under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for treating inflammation, degenerative joint complaints, cartilaginous degeneration and gastrointestinal sensitivity or irritation, does not provide enablement for treating cancerous tumors. In response, Applicants have deleted the reference in claim 22 to treatment of cancerous tumors.

The Examiner has also rejected all of pending claims 1-19 and 22-34 under 35 U.S.C. § 112, second paragraph, as being indefinite, for various reasons. Below are set forth the Examiner's rejections, and Applicants response to each rejection is stated below the rejection. In view of these responses, Applicants respectfully request that all of these srejection be withdrawn.

(i) The Examiner stated that claims 5-7 recite the trademarks Enzogenol and Pycnogenol instead of the generic products, i.e., bark extracts and antioxidants. In response, Applicants have herein amended claims 5-7 so that they no longer refer to the trademarks Enzogenol and Pycnogenol but rather to the generic product, bark extract.

(ii) The Examiner stated that there is insufficient antecedent basis in the Markush grouping of the anti-inflammatory agent in claim 2 for the limitation in claim 5 that the anti-inflammatory agent can be "either or both of ... pharmacologically active shark cartilage extract". In response, Applicants have herein amended claim 2 such that the second element of the first Markush grouping of anti-inflammatory agents is "shark cartilage, or pharmacologically active shark cartilage extract, or both", thus supplying sufficient antecedent basis for the

limitation in claim 5. The additional language, which is discussed for example at page 4, lines 19-24 of the specification, does not consist of new matter.

(iii) The Examiner stated that claim 7 is indefinite because it refers to Enzogenol and "its equivalents", and the specification does not define what is the trademark Enzogenol and what are equivalent bark extracts. In response, Applicants note that, as discussed above, claim 7 has herein been amended to no longer refer to the trademark Enzogenol but rather to the generic product, bark extract. Claim 7 now refers "one or more anti-oxidants other than bark extracts".

(iv) The Examiner stated that it is unclear in claims 12, 26 and 27 whether "compounds providing ..." is part of the Markush grouping of "components" or is part of a separate Markush grouping. In response, Applicants have amended these claims to clarify the Markush grouping, such that it includes the elements manganese, zinc, iron, magnesium, selenium, calcium, copper, potassium and cobalt, as well as pharmaceutically acceptable forms thereof.

(v) The Examiner stated that the term "addressing" in claims 15, 18 and 32-34 is unclear and is not defined in the specification. In response, Applicants have herein amended claims 15, 18 and 32-34 to replace the term "addressing" with "treating".

(vi) The Examiner stated that the word "or" between the words "bolus" and "tablet" in the Markush grouping of claim 16 is confusing. In response, Applicants have herein amended claim 16 such that "bolus" and "tablet" are two separate elements of the Markush grouping of claim 16 and are separated by a comma.

(vii) The Examiner stated that, in claim 22, the terms "degenerative joint complaints" and "other cartilaginous degeneration" are confusing. The Examiner queries whether the invention treats the complaint or the degenerative joint and what other "cartilaginous degeneration" is being treated besides that mentioned. In response, Applicants have amended claim 22 to clarify that the invention treats degenerative joints, as well as cartilaginous degeneration in general, such as that not necessarily related to degenerative joints.

(viii) The Examiner stated that the Markush grouping for the composition in claim 22 is confusing due to the use of "and/or" before "pharmacologically active shark cartilage extract". In response, Applicants have amended claim 22 to return the structure that was inadvertently modified in the Preliminary Amendment submitted on January 18, 2002 in order to clarify the Markush grouping elements. Now, the composition comprises two or more of (i) a green-lipped mussel extract (GLME), or a pharmacologically active green lipped mussel product, or both, (ii) shark cartilage, or pharmacologically active shark cartilage extract, or both, and (iii) an antioxidant bark extract.

(ix) The Examiner stated that the Markush grouping for the composition in claims 1-2, 14 and 30-31 is confusing due to the use of "and/or" before the first two terms and an "and" between the second and third terms. In response, Applicants have amended claims 1-2, 14 and 30-31 to clarify the Markush grouping elements. Namely, in claims 1 and 2, the first element of the first Markush grouping of anti-inflammatory agents has been amended to read "green-lipped mussel extract (GLME), or a pharmacologically active green lipped mussel product, or both". Now, the at least one anti-inflammatory agent in claims 1 and 2 is selected from the group comprising (i) green-lipped mussel extract (GLME), or a pharmacologically active green lipped mussel product, or both, and (ii) shark cartilage (or, in claim 2, pharmacologically active shark cartilage extract, or both). Similarly, claims 14, 30 and 31 have been amended to recite that the anti-inflammatory is other than green-lipped mussel extract (GLME), a pharmacologically active green-lipped mussel product, both green-lipped mussel extract (GLME) and a pharmacologically active green-lipped mussel product, and shark cartilage.

Prior Art Rejections

The Examiner rejected claims 1-5, 10, 13-19, 22, 24, 28 and 31-34 under 35 U.S.C. § 103(a) as being obvious over Great Britain Patent Appl. No. 2347349 (Croft) and U.S. Patent No. 6,028,118 (Dupont et al.). According to the Examiner, Croft teaches a synergistic composition comprising green-lipped mussel extract and glyosaminoglycan (chondroitin sulphate) that may be administered orally for treating osteoarthritis or rheumatoid arthritis and for treating inflammation in a non-human animal. The Examiner states that Croft lacks an

enhancing agent, but that Dupont et al. teach a method of treating arthritis by administering an extract of shark cartilage having anti-angiogenic and anti-inflammatory activities. The Examiner concludes that it would have been obvious to add the shark cartilage extract of Dupont et al. to the composition of Croft to form a third composition that is to be used for the very same purpose and for enhancing blood flow to the suffering area.

The Examiner rejected claims 12, 26, 27, 29 and 30 under 35 U.S.C. §103(a) as being obvious over Croft in view of Dupont et al. and further in view of U.S. Patent No. 6,255,295 (Henderson et al.). The Examiner states that, as applied above, Croft and Dupont et al. lack preferred additional pharmaceutically active agents, but that Henderson et al. teach compositions, such as Chondroitin sulfate in combination with glucosamine as well as Vitamins B12 and B6, folic acid, dimethylglycine, trimethylglycine, and others, for the treatment, protection, repair and reduction of inflammation of connective tissue for conditions such as arthritis. The Examiner concludes that it would have been obvious to add vitamin B12, as taught by Henderson, to the composition of the combined references because of the expectation of promoting the production of connective tissue matrix.

The Examiner also rejected claims 9 and 23 under 35 U.S.C §103 as being obvious over Croft in view of Dupont et al. and further in view of Church (Velvet Antler: It's Historical Medical Use). The Examiner states that Croft and Dupont et al. lack deer velvet, but that Church teaches that glycosaminoglycans in the water soluble fractions of velvet antlers have growth promoting effects on cells, and anti-inflammatory properties. The Examiner concludes that it would have been obvious to add deer velvet, as taught by Church, to the composition of the combined references because of the expectation of achieving a composition that further combats the inflammatory response, thereby easing arthritis.

The Examiner further rejected claims 7, 8 and 25 under 35 U.S.C. §103(a) as being obvious over Croft in view of Dupont et al. and further in view of U.S. Patent No. 5,843,919 (Burger). According to the Examiner, Croft and Dupont et al. lack anti-oxidants, but Burger teaches that Vitamin E can to be added to compositions comprising glucoaminoglycan that treat arthritis, as additional components. The Examiner concludes that it would have been obvious to

add Vitamin E, as taught by Burger, into the composition of the combined references because of the expectation of achieving cells that are protected against free-radical damage and are healthier.

Finally, the Examiner has rejected claim 11 under 35 U.S.C. § 103(a) as being obvious over Croft in view of Dupont et al. and further in view of U.S. Patent No. 4,801,453 (Kosuge et al.). According to the Examiner, Croft and Dupont et al. lack an effective amount of green-lipped mussel extract to provide gastro-intestinal protection, but Kosuge et al. teach compositions comprising GLME for treating arthritis and gastro-intestinal irritation, conditions, lesions, and/or ulcer formation. The Examiner concludes that it would have been obvious to teach the composition of the combined references in an amount effective to provide gastro-intestinal protection because Kosuge et al. teach that compositions comprising GLME can be formulated to treat gastro-intestinal disorders or arthritis.

Applicants traverse the Examiner's rejection.

Applicants' invention is directed to a composition for administration to animals that comprises a combination of at least one anti-inflammatory agent selected from the group consisting of (i) GLME or a pharmacologically active green lipped mussel product, or both, and (ii) shark cartilage, or pharmacologically active shark cartilage extract, or both; with at least one enhancing agent selected from the group consisting of (i) a bark or plant product or bark or plant extract, exhibiting any one of antioxidant, anti-arthritic, and anti-inflammatory properties, and (ii) shark cartilage. In this combination, for a composition including just one member from each group, the selected members must be different.

In Applicants' invention, the combination of these elements provides a synergistic effect that is not found, and that would not be thought to exist, with any of the elements individually. Although similar compounds are present, it is likely that the improved effect of the composition of the present invention over either of the two ingredients when utilized alone is due to the efficacy enhancing nature of compounds other than glycosaminoglycans present in the shark cartilage.

In the Office Action, the basis for all rejections is a combination of the Croft and Dupont et al. references. According to the Examiner, it would have been obvious at the time the invention was made to add the shark cartilage extract of Dupont et al. to the composition of Croft comprising green-lipped mussel extract and glyosaminoglycan to form a third composition that is to be used for treating inflammation in a non-human animal and for enhancing blood flow to the suffering area. Applicants disagree. Whereas both Dupont et al. and Croft mention treatment of inflammatory conditions, a great many other pharmaceutical compositions also exist to treat inflammation, and there is nothing in the prior art that even suggests that it may be useful to include shark cartilage within the composition of Croft in order to enhance the actions of green-lipped mussel extract therein. Similarly, there is nothing in the prior art that even suggests that it may be useful to include bark extract in order to enhance the actions of either green-lipped mussel extract or shark cartilage. This lack of suggestion is because shark cartilage and green-lipped mussel extract contain the same active ingredients, and one would not be motivated to combine two remotely-derived substances that have the same active ingredients.

DuPont does not teach the nature of the active component in shark cartilage but states throughout that the anti-collagenolytic factor present is of less than 10kDa, which means that it is not likely to be glycosaminoglycans. Perhaps the factors of lighter molecular weight augment the activity of the GLME to a greater extent than they do the glycosaminoglycans present when bound in cartilage, hence the greater anti-inflammatory activity of the combination.

While the Examiner alleges that one of ordinary skill in the art would be motivated to combine the respective teachings of Croft and of Dupont et el. because they both provide compositions for treating inflammation, Applicants respectfully point out that, despite this, the two references are still quite far apart as far as their ingredients are concerned and one would not be motivated to combine the shark cartilage extract of Dupont et al. with the composition of Croft comprising green-lipped mussel extract and glyosaminoglycan. The synergistic effect of Applicants' claimed composition is surprising and is not alleged or even suggested in the cited references. Accordingly, Applicants respectfully request that the Examiner withdraw her rejections of claims 1-19 and 22-34.

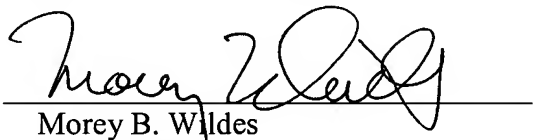
Conclusion

According to currently recommended U.S. Patent and Trademark Office policy, the Examiner is specifically authorized to contact the undersigned in the event that a telephone interview would advance the prosecution of the case.

Reconsideration of the present application, as amended, is requested. Applicants respectfully submit that all the claims pending in this application are patentable. An early and favorable action on the merits is earnestly solicited.

An early and favorable action on the merits is earnestly solicited.

Respectfully Submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

Morey B. Wildes
Reg. No. 36,968

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th Floor
New York, NY 10018
(212) 736-1940